Remarks:

Claims 1-15 and 17-24 remain in this application. Claim16 has been canceled.

Claim 6 stands rejected under 35 U.S.C. 112 as being indefinite. Applicants have amended the dependency of claim 6 to address the cited informality. Reconsideration and withdrawal of the rejection is respectfully requested.

The specification stands "objected to as failing to provide proper antecedent basis for the claimed subject matter. . . . For example, means for preventing, means for anchoring, member, means for spacing, engagement member, body, retention member, anchor portion, are not supported."

With regard to the term "member" used in claims 4, 5, and 6, Applicant cites the amended specification at paragraph [0024] line 1 in which Applicant refers to a "first member, or retention member 60, ..." Applicant did not precede "member" by "first" in claims 4, 5, and 6 because there are no claims depending from them that introduced the second member and it was thought unnecessary. However, to provide clear antecedence in the specification as required by examiner, claims 4, 5, and 6 have been amended to substitute "first member" for "member". Note that claim 7 refers to "first and second members" which finds antecedence in the specification at paragraph [0024] (first member) and paragraph [0025] (second member).

With regard to the term "engagement member" used in claims 9, 10, and 11, Applicant cites the specification at paragraphs [0019], [0020], [0027], and [0028]. The last two sentences of paragraph [0019] discuss projections for engaging the implant in a general sense to introduce the concept of radial spacing. Sentences 6 and 7 of paragraph [0020] likewise introduce an alternative engagement member concept for radial spacing. The rest of paragraph [0020] gives

an example of a positioner with engagement members. Paragraphs [0027] and [0028] describe the specific structural examples of radial spacing. However, Applicant did not use the specific term "engagement member" in the specification. Instead, Applicant referred to "engagement features providing for radial spacing" at the end of paragraph [0027]. Applicant has amended the specification to include the term "spacing member" in the description of each of the members "for spacing" discussed in these paragraphs. Amended claim 9 now refers to "spacing member" rather than "engagement member" and thus finds support in the specification.

With regard to the term "body" used in claims 7, 9, 12, and 22. Applicant asserts that the term "body" is universally understood as a basic structural element in claim language. Furthermore, the term "body" finds support in the specification at paragraph [0011] in which one aspect of the invention is described in terms of

> "a positioner include[ing] an "L"-shaped **body** having a first leg positionable over a portion of the femoral hip implant relative to the canal axis. A second leg is simultaneously positionable adjacent the canal wall to maintain a predetermined spacing between the femoral hip implant and the canal wall."

And likewise in paragraph [0019] where "body" is used to describe an illustrative example:

> "For example, the positioner may include a **body** with a plurality of legs extending downwardly . . . ."

With regard to the term "retention member" used in claims 18 and 24, Applicant has replaced the term in paragraphs [0010] and [0012] and in claims 18 and 24 with "positioner" to better parallel the language used in the rest of the specification and claims.

With regard to the term "anchor portion" used in claims 15, 18 and 21, Applicant has replaced it with "second member" and "anchor member" which find support in the specification in paragraphs [0019], [0025], [0026], and [0027].

Although examiner did not specifically require amendment to the term "retention portion" used in claims 15, 16, 17, and 18, Applicant has similarly replaced it with "first member" and "retention member" for consistency and clarity. This amendment finds support in the specification in paragraphs [0019], [0024], [0025], [0026], and [0027].

With regard to the "means for" elements in the claims, Applicant does not understand Examiner's contention that these elements lack support. Referring to MPEP 2181, paragraphs II-IV, for guidance produces an extensive compendium of case law establishing that the corresponding structure of a means-plus-function limitation must be disclosed in the specification in a way that one skilled in the art will understand what structure will perform the recited function. The disclosure may be implicit or inherent and the drawings may provide the written description. MPEP 2181, paragraph III further states that:

> The following guidance is provided to determine whether applicant has complied with the requirements of 35 U.S.C. 112, second paragraph, when 35 U.S.C. 112, sixth paragraph, is invoked: (A) If the corresponding structure, material or acts are described in the specification in specific terms (e.g., an emitter-coupled voltage comparator) and one skilled in the art could identify the structure, material or acts from that description, then the requirements of 35 U.S.C. 112, second and sixth paragraphs and are satisfied. See Atmel, 198 F.3d at 1382, 53 USPQ2d 1231.

Applicant presents in broad terms in paragraph [0018] a positioner that "prevent[s] the femoral hip implant from rising out of the femoral canal beyond a predetermined position while permitting subsidence of the femoral hip implant into the femoral canal." This positioner is then further defined in paragraphs [0019], [0024], [0029], and [0030].

For instance, in paragraph [0019], an exemplary positioner is described as having "a portion overlying a portion of the implant in the direction of the longitudinal axis of the femoral canal so that the implant is prevented from rising by abutment against the overlying portion". It appears that the overlying portion in this example clearly performs the function of the "means for preventing the femoral hip implant from rising our of the femoral canal" since this exact language is used in paragraph [0018] and very similar language with an explanation of how it performs the function (by abutment against the overlying portion) is presented in paragraph [0019]. Paragraph [0019] further discloses that the positioner may have one or more members extending over the implant and that the positioner and members may take a variety of shapes.

Paragraph [0024] describes in detail an illustrative example with reference to the drawing in which a "the positioner 10 includes a first member, or ~~top~~ retention member 60, positionable over a portion of the femoral component 36 to prevent the femoral component 36 from rising out of the femoral canal beyond a predetermined position." Again, this is an exact recitation of the means-for functional language used in Claim 1, leaving no doubt as to what structure will perform the recited function.

Paragraphs [0029] and [0030] further describe the illustrative example as having "a unitary, "T"-shaped construct" that "once . . . attached to the cement 52 and/or femur 16, . . . will prevent the femoral component 36 from rising up out of the canal 14 beyond a predetermined position as the femoral component 36 abuts the positioner 10. However, the positioner 10 permits the femoral component 36 to subside down into the canal 14."

Finally, Applicant asserts that notwithstanding the association in the specification of the exact functional language of the means-plus-function limitation with specific structural

examples, the drawings clearly depict to one skilled in the art "means for preventing the femoral hip implant from rising out of the femoral canal beyond a predetermined position while permitting subsidence of the femoral hip implant down into the femoral canal".

Similarly, "means for anchoring" finds support throughout the specification.

Paragraph [0018] recites that

> "[t]he positioner may be anchored to the bone of the femoral canal and/or anchored in cement placed within the femoral canal . . . . For example, the positioner may be anchored in cement to limit upward motion of the implant relative to the cement while permitting the implant to subside into the cement in response to axial loading."

and, more specifically, paragraph [0019] recites that

> "The positioner may include multiple members with one or more members extending over a portion of the implant and one or more members extending into the bone and/or cement to anchor the positioner."

and, with reference to the illustrative example of the drawings, paragraph [0025] recites

> "The positioner 10 further includes a **second member, or ~~lateral leg~~ anchor member 62, for anchoring the ~~top~~ retention member 60 relative to the canal 14 and/or cement 52**. In the illustrative embodiment, the ~~lateral leg~~ anchor member 62 extends at an angle from the ~~top~~ retention member 60 and is embedded in the cement 52 to anchor the ~~top~~ retention member 60 relative to the cement 52. However, the ~~lateral leg~~ anchor member 62 may also be anchored in bone, for example by driving it into the femur 16 adjacent the canal 14 and thus anchor the ~~top~~ retention member 60 relative to the canal 14. Scallops 63 in the ~~lateral leg~~ anchor member 62 create a positive engagement with the cement 52 and/or femur 16 to enhance the fixation of the ~~lateral leg~~ anchor member 62."

In this example, the retention member 60 is the "means for preventing" as described above and the lateral leg 62 is the "means for anchoring the means for preventing relative to the femoral canal" as recited in Claim 1.

Similarly, "means for spacing" finds support throughout the specification.

Paragraph [0011] recites that

> "A second leg is simultaneously positionable adjacent the canal wall to maintain a predetermined spacing between the femoral hip implant and the canal wall."

and, with reference to the illustrative example of the drawings, paragraph [0027] recites

> Furthermore, **the radial spacing of the boss 70 and one or more of the legs 62, 64, 66 maintains a predetermined spacing between the femoral component 36 and canal 14 wall 20**. In the illustrative embodiment, the boss 70 and ~~lateral leg~~ anchor member 62 form an "L"-shaped spacer with a ~~top~~ retention member 60 positionable over and engageable with a portion of the femoral component 36 and a ~~lateral leg~~ **anchor member 62 positionable adjacent the canal 14 wall 20 to space the femoral component 36 from the lateral aspect 24 of the canal 14 wall 20**. Where present, the anterior 64 and posterior 66 legs may likewise provide a predetermined radial spacing from the anterior 26 and posterior 28 aspects of the canal 14 wall 20.

Paragraph [0025] uses nearly identical language as the limitation in Claim 2 which states "means for spacing the femoral hip implant a predetermined distance from the canal wall."

Since the specification clearly associates the functional language of the means-plus-function elements of the claims with structure that will perform the recited functions and furthermore since the drawings clearly depict means for performing the claimed functions, Applicant respectfully requests withdrawal of the objection to the specification for failing to support the means-plus-function elements.

Claims 1-4, 6, 15-17 and 24 stand rejected under 35 U.S.C. 102(b) as being anticipated by Carpenter (U.S. 5,425,768). Applicants respectfully traverse the rejection.

Carpenter discloses a conventional prosthesis 20 including a conventional distal spacer 40. The spacer 40 is used to ensure that the end portion of the prosthesis stem 22 is appropriately centered within the intramedullary canal of the femur, i.e. spaced evenly from the side walls of the canal. Uniform spacing enables the formation of a uniform cement mantle. It appears that the Examiner has inadvertently misread or misconstrued Carpenter's disclosure. The spacer 40 does not server to retain the prosthesis 20 within the canal, a feature of the claimed invention. Moreover, the spacer 40 is wedged into the femoral canal and does not appear to allow for

subsidence of the prosthesis 20, another feature of the claimed invention. Still further, Carpenter fails to disclose or suggest the recited anchoring means. The Examiner appears to assert that the same spacer 40 serves multiple purposes. Crest 62 of the spacer 40 merely serves to center the spacer within the canal while permitting the cement to pass the distal spacer 40. See col. 3, line 63-68.

Carpenter's disclosure fails to identify the problem of preventing the prosthesis from rising out of the femoral canal, let alone disclosing a solution for addressing this problem. Assuming, for the sake of argument, that a prosthesis according to Carpenter were to experience a force urging the prosthesis out of the canal, it is likely that the connection between the spacer 40 and the stem 22 of the prosthesis 20 would be broken since the distal spacer is coupled to the stem 22 merely "by insertion of the post 46 into the bore 52." Column 3, lines 36-40. This coupling is arranged to withstand forces tending to press the spacer into the stem during insertion but not to prevent upward displacement of the stem relative to the spacer. Once in place, the spacer "becomes indistinguishable from the surrounding cement" and no longer has any positioning function.

For at least these reasons, Applicants respectfully request that the rejection of claims 1-4, 6, 15-17 and 24 be reconsidered and withdrawn.

Claims 1-10 and 15-24 stand rejected under 35 U.S.C. 102(b) as being anticipated by Link (U.S. 4,698,063). Applicants respectfully traverse the rejection.

Link discloses a femoral prosthesis 7 having a removable collar 10. Link discloses two embodiments of the support collar 10, a first embodiment is depicted in FIGS. 1-5 and a second embodiment is depicted in FIG. 6. Neither embodiment allows subsidence of the femoral

prosthesis 7 distally into the cement, a feature of the claimed invention. Notably, the support collar 10 is rigidly attached to the stem 6 of the femoral prosthesis 7. In the first embodiment (best seen in FIG. 5) a tongue 17 in groove 19 connection between the support collar 10 and the femoral prosthesis 7 prevents the femoral prosthesis 7 from subsiding distally into the cement. In the second embodiment (FIG. 6) a screw 18 projects into engagement with the neck 8 to prevent relative motion between the femoral prosthesis 7 and the support collar 10 and hence prevents the femoral prosthesis 7 from subsiding distally into the cement. Moreover, the second embodiment also utilizes tongue 17 in groove 19 connection between the support collar 10 and the femoral prosthesis 7, further preventing the femoral prosthesis 7 from subsiding distally into the cement.

For at least these reasons, Applicants respectfully request reconsideration and withdrawal of the rejection of Claims 1-10 and 15-24.

Claims 1-7, 15-20, 22 and 23 stand rejected under 35 U.S.C. 102(b) as being anticipated by Mathys (U.S. 5,571,202). Applicants respectfully traverse the rejection.

Mathys discloses a prosthesis 10 to allow anchoring a screw 9 in the outer cortex of the femur. Mathys explicitly teaches:

When the screw 9 is fully threaded and anchored in the prosthesis collar and the bone, the connection between bone and prosthesis is firmer mechanically because displacements between the screw 9 and the bone as well as the prosthesis collar are prevented. Col. 3, line 65 through Col. 4, line 2.

Accordingly, Mathys not only fails to disclose or suggest a device which permits the femoral prosthesis 7 to subside distally into the cement, but in fact teaches away from this aspect of the

claimed invention. For at least this reason, Applicants respectfully request reconsideration and withdrawal of the rejection of Claims 1-7, 15-20, 22 and 23.

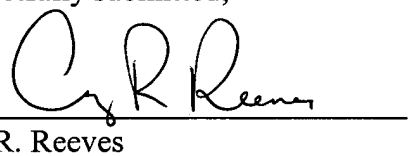
Upon reviewing Examiners rejections, it appears that claims 11-14 have not been addressed by examiner. Applicant requests clarification as to whether these claims stand as allowed or rejected.

It is believed that the above Remarks represent a complete response to the Office Action and that the Application is now in condition for allowance, and such favorable determination is requested.

In the event Applicant has overlooked the need for an extension of time or payment of fee, Applicant hereby petitions therefore and authorizes that any charges be made to Deposit Account No. 50-2779, ZIMMER TECHNOLOGY, INC.

Applicant respectfully requests that a timely Notice of Allowance be issued in this case.

Respectfully submitted,

By: 

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